Common Sense Initiative

Mike DeWine, *Governor*
Jon Husted, *Lt. Governor*

Joseph Baker, *Director*

Comments on the proposed rules will be accepted until close of business on June 24, 2024. Please send all comments to the following email address:
RuleComments@pharmacy.ohio.gov

In addition, please copy your comments to: CSIPublicComments@governor.ohio.gov

Business Impact Analysis

Agency, Board, or Commission Name: Ohio Board of Pharmacy

Rule Contact Name and Contact Information: Summer Corson
Summer.Corson@pharmacy.ohio.gov

Regulation/Package Title (a general description of the rules' substantive content):

Recordkeeping

Rule Number(s): 4729:5-5-01, 4729:5-5-04

Date of Submission for CSI Review: 6/6/2024

Public Comment Period End Date: 6/24/2024

Rule Type/Number of Rules:

New/___ rules

No Change/____ rules (FYR? ___)

Amended/__2__ rules (FYR? _Y__)

Rescinded/____ rules (FYR? ___)

Common Sense Initiative

Mike DeWine, *Governor*
Jon Husted, *Lt. Governor*
Joseph Baker, *Director*

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☒ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☐ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☒ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed

amendments.

Amend

- 4729:5-5-01 – Definition section for outpatient pharmacy rule chapter. Rule is being amended to ensure no conflict with proposed amendments to 4729:5-5-04.

- 4729:5-5-04 – Provides the record keeping requirements for outpatient pharmacies.

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

   The proposed rules are authorized by sections 4729.26 and 3719.28 of the Ohio Revised Code.

4. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**
   If yes, please briefly explain the source and substance of the federal requirement.
   These rules do not implement a federal requirement.

5. **If the regulation implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**
   N/A

6. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**
   Section 4729.26 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules governing the practice of pharmacy and distribution of dangerous drugs.

   Section 3719.28 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules prescribing the manner of keeping and the form and content of records to be kept by persons authorized to manufacture, distribute, dispense, conduct research in, prescribe, administer, or otherwise deal with controlled substances.

7. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**
   The success of the regulations will be measured by having rules written in plain language, licensee compliance with the rules, and minimal questions from licensees regarding the

provisions of the rules.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**
   If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.
   No.

Development of the Regulation

9. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
   If applicable, please include the date and medium by which the stakeholders were initially contacted.
   The rules in this package were distributed electronically for initial public comment to all Board of Pharmacy licensees.

   Prior to filing with CSI, the rules were also reviewed and approved by the Board of Pharmacy.

10. **What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**
    Rule 4729:5-5-04 was further amended after the stakeholder comment period as follows:
    - Authorizes the use of hardcopy signatures and manual records in the event of an outage of a computerized record keeping system.
    - Permits the use of hardcopy signatures and manual records for drug compounding and ancillary services.

11. **What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**
    Scientific data was not used to develop or review this rule.

12. **What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?**
    Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.

As the regulations are essential to protecting the public's safety by ensuring complete and accurate pharmacy records, the Ohio Board of Pharmacy did not consider any regulatory alternatives.

13. **What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**
    The Board of Pharmacy's Director of Policy and Communications reviewed the proposed rules to ensure that the regulations do not duplicate another Ohio Board of Pharmacy regulation.

14. **Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**
    The rules will be posted on the Board of Pharmacy's web site, information concerning the rules will be included in materials e-mailed to licensees, and notices will be sent to associations, individuals, and groups. Board of Pharmacy staff are also available via phone or email to answer questions regarding implementation of the rules. In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections.

    Board of Pharmacy staff receive regular updates on rules via internal email updates, regular staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, and feedback from the Board's legal department for every citation submitted.

Adverse Impact to Business

15. **Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:**
    a. **Identify the scope of the impacted business community, and**
       Outpatient pharmacies operating in Ohio.

    b. **Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).**
       The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a representative business. Please include the source for your information/estimated impact.

- 4729:5-5-01 – This is a definition section and does not have any adverse impact to licensees.
- 4729:5-5-04 – Provides the record keeping requirements for outpatient pharmacies. The rule requires all pharmacies to utilize a computerized recordkeeping system, to be able to capture positive identification electronically. This will require pharmacies that do not have the capability to make upgrades to their systems. Any pharmacy that may experience economic hardship as a result of this requirement may apply for a waiver to the Board.

16. **Are there any proposed changes to the rules that will <u>reduce</u> a regulatory burden imposed on the business community? Please identify. *(Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors).***

    4729:5-5-04 – Allows outpatient pharmacies to submit a waiver of the requirement for electronic positive identification if the pharmacy can demonstrate the requirement would impose an undue economic hardship to the pharmacy.

17. **Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?**
    The Board determined that the regulatory intent justifies the impact on business because the regulations protect and promote public safety by ensuring complete and accurate pharmacy records.

Regulatory Flexibility

18. **Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.**
    Allows outpatient pharmacies to submit a waiver of the requirement for electronic positive identification if the pharmacy can demonstrate the requirement would impose an undue economic hardship to the pharmacy.

19. **How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?**
    The Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure of a standard of care in the practice of pharmacy by pharmacists and pharmacy interns is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

20. What resources are available to assist small businesses with compliance of the regulation?

Board of Pharmacy staff is available by telephone and e-mail to answer questions. Board staff members also provide presentations to groups and associations who seek updates on current regulations and host regional meetings to discuss changes to Ohio laws and rules. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

Rule 4729:5-5-01 | Definitions. (AMEND)

…

(I)

(1) "Positive identification" means a method of identifying a person that does not rely on the use of a private personal identifier such as a password, but must use a secure means of identification that includes any of the following**, as authorized under this chapter of the Revised Code:**

(a) A manual signature on a hard copy record;

(b) A magnetic card reader;

(c) A bar code reader;

(d) A biometric method;

(e) A proximity badge reader;

(f) A board approved system of randomly generated personal questions;

(g) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who performed the action requiring positive identification. The printout must be maintained for three years and made readily retrievable; or

(h) Other effective methods for identifying individuals that have been approved by the board.

…

Rule 4729:5-5-04 | Record keeping. (AMEND)

(A) There shall be positive identification of the licensed or registered individuals responsible for performing the following activities authorized under Chapter 4729. of the Revised Code and agency 4729 of the Administrative Code:

(1) Prescription information entered into the record keeping system. ~~**This provision shall take effect one-year from the effective date of this rule.**~~

(2) Verification by the pharmacist of the prescription information entered into the record keeping system.

(3) Prospective drug utilization review, which shall be captured as a standalone action or as part of either:

(a) The pharmacist verification of prescription information in paragraph (A)(2) of this rule; or

(b) The dispensing process in paragraph (A)(4) of this rule.

(4) Dispensing.

(5) Compounding.

(6) Administering immunizations pursuant to section 4729.41 of the Revised Code.

(7) Administering injectable drugs pursuant to section 4729.45 of the Revised Code.

(8) Prescription information transcribed from an order received by telephone, facsimile, or recording device.

(9) Any changes or annotations made to a prescription.

(B) All records maintained in accordance with this rule shall be uniformly maintained for a period of three years.

(C) Record keeping systems shall provide immediate retrieval via digital display and hard copy printout or other mutually agreeable transfer medium of information for all prescriptions dispensed within the previous twelve months and shall provide, in a manner that is readily retrievable, information on all prescriptions dispensed beyond the previous twelve months but within the previous three years. This information shall include, at a minimum, the following data:

(1) The original prescription number;

(2) Date of issuance of the original prescription order by the prescriber;

(3) Full name of the patient for whom the drug is intended; or, if the patient is an animal, the last name of the owner, name of animal (if applicable), and species of the animal or animals;

(4) Residential address, including the physical street address and telephone number of the patient or owner;

(5) Full name and address of the prescriber, including the physical address of the prescriber's practice location;

(6) The prescriber's credential (MD, DDS, DVM, etc.), if indicated on the prescription;

(7) Directions for use;

(8) The brand name, if any, or the generic name and the name of the manufacturer or distributor or national drug code of the drug or device dispensed;

(9) The strength, dosage form, and quantity of the drug or device dispensed;

(10) The prescriber's federal drug enforcement administration number, if applicable;

(11) The positive identification of the persons performing specific actions pursuant to paragraph (A) of this rule;

(12) The total number of refills authorized by the prescriber;

(13) The date of dispensing;

(14) The refill history of the prescription, including all of the following:

(a) The prescription number;

(b) The brand name, if any, or the generic name and the name of the manufacturer or distributor or national drug code of the drug or device dispensed;

(c) The date(s) of dispensing; and

(d) The quantity dispensed.

(D) **Except as provided in paragraphs (N) and (O) of this rule,** a pharmacy that utilizes a computerized system to dispense dangerous drugs ~~**that is unable to**~~ **shall** electronically document positive identification in accordance with paragraph (A) of this rule**. If a pharmacy does not use a computerized system to dispense dangerous drugs or has obtained a**

waiver pursuant to paragraph (N) of this rule, the pharmacy shall be required to maintain hard copy documentation. Hard copy documentation shall be provided by each registered or licensed individual who makes use of such system by one of the following methods:

(1) A hard copy printout of each day's prescription data.

(a) The printout shall include, at a minimum, the following data:

(i) Date of dispensing;

(ii) Prescription number;

(iii) Patient name;

(iv) Name, strength, and quantity of drug dispensed;

(v) Identification of the pharmacist or pharmacy personnel responsible for any activity described in paragraph (A) of this rule;

(vi) Identification of the pharmacy; and

(vii) Identification of controlled substances.

(b) The printout must be verified, dated, and signed by each individual responsible for any activity described in paragraph (A) of this rule. The printout must be verified and manually signed by the individual within a reasonable timeframe to ensure the accuracy of the record.

(c) If the printout is prepared at a location other than where the drug was dispensed, the printout must be provided to the licensed location within three business days of the date on which the drugs were dispensed. Such printouts must be verified and signed by each individual responsible for any activity described in paragraph (A) of this rule within twenty-four hours of the date the printout is received by the individual.

(d) The printout must be readily retrievable and maintained in chronological order in a separate file at the licensed location where the drug was dispensed for a period of three years from the date of dispensing.

(e) The signed printout may be stored electronically in accordance with paragraph (E) of this rule.

(2) A tamper evident log book.

(a) Each individual pharmacist involved in dispensing drugs must enter into a tamper evident log book the following data for each prescription dispensed:

(i) Date of dispensing;

(ii) Prescription number;

(iii) Patient name;

(iv) Name, strength, and quantity of drug dispensed;

(v) Identification of the pharmacist and pharmacy personnel responsible for any activity described in paragraph (A) of this rule;

(vi) Identification of controlled substances.

(b) Each individual responsible for any activity described in paragraph (A) of this rule shall review this information at the end of each day, or at the end of the individual's shift, and must either:

(i) Manually sign a statement in the log book attesting to the fact that the prescription information entered into the computer that day and recorded in the log book has been reviewed by the individual and is correct as shown; or

(ii) Manually initial each entry of the log book to indicate that the prescription information entered into the computer that day and recorded in the log book has been reviewed by the individual and is correct as shown.

(c) The log book must be readily retrievable and maintained at the licensed location where the drug was dispensed for a period of three years from the date of dispensing.

(E) A signed printout that is maintained in accordance with paragraph (D) of this rule may be electronically created and maintained, provided the system creates and maintains the printout in accordance with the following:

(1) All information in the printout shall be scanned in full color (i.e., retains color information and/or color graphics in the document) via technology designed to capture information in one form and reproduce it in an electronic medium presentable and usable to an end user;

(2) A record or image once created shall be unalterable but may be annotated as necessary so long as the original record or image is still available for review and the individual that made the annotation is noted;

(3) Contains security features to prevent unauthorized access to the records;

(4) Contains daily back-up functionality to protect against record loss.

(F) In addition to the immediate retrieval and production of prescription information required by paragraph (C) of this rule, an outpatient pharmacy that utilizes a computerized record keeping system shall comply with the following:

(1) Make readily retrievable the following information:

(a) An electronic record in a character-delimited or fixed-width ASCII text file or other mutually acceptable format that contains any requested data fields the pharmacy is responsible for maintaining pursuant to all federal and state laws, rules and regulations; and

(b) A hard copy printout sorted by any requested data fields that the pharmacy is responsible for maintaining pursuant to all federal and state laws, rules, and regulations.

(2) Make readily available upon request by an individual authorized by law to access such records any of the following:

(a) A printout; or

(b) An electronic record and a definition file describing the file layout and column width, if applicable.

(3) All computerized record keeping systems shall be able to capture records edited by authorized personnel and maintain an audit trail.

(G) In the event that a pharmacy utilizes a computerized record keeping system that experiences an outage, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of prescription orders.

(1) This auxiliary procedure must ensure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is recorded and retained.

(2) This auxiliary procedure may utilize hardcopy records and manual signatures to capture positive identification.

(3) Nothing in this paragraph shall preclude a pharmacist from dispensing a refill if, in the exercise of the pharmacist's professional judgement, failure to dispense or sell the drug to the patient could result in harm to the health of the patient.

(H) Prescriptions entered into a computer system that are not dispensed shall meet all of the following requirements:

(1) The complete prescription information must be entered in the computer system;

(2) The information must appear in the patient's profile;

(3) There is positive identification of the person who is responsible for entering the prescription information into the system and the pharmacist responsible for verifying the prescription information in accordance with paragraph (A) of this rule;

(4) The prescription must be assigned a prescription number; and

(5) The original prescription is filed according to rule 4729:5-5-03 of the Administrative Code.

(I) Records shall be maintained for three years and made readily retrievable for all immunizations administered in accordance with section 4729.41 of the Revised Code and rules 4729:1-3-02 and 4729:2-3-03 of the Administrative Code and shall include the following information:

(1) Full name and address of the patient;

(2) Patient's date of birth or age;

(3) Patient's applicable allergy information;

(4) Date of administration;

(5) Name, strength, and dose of the immunization administered;

(6) Lot number and expiration date of the immunization;

(7) Route of administration;

(8) Location of the injection site;

(9) Positive identification of the administering pharmacist or the administering pharmacy intern **or pharmacy technician** and supervising pharmacist;

(10) Identification of the patient, parent, or legal guardian of the patient who gives informed consent to administer the immunization.

(J) Immunization records may be electronically created and maintained if done so in accordance with the standards set forth in paragraph (E) of this rule.

(K) A pharmacist may document the pharmacist's own administration of an immunization or an immunization administered by a pharmacy intern the pharmacist is personally supervising on a prescription form, which may be assigned a number for record keeping purposes.

(L) Records shall be maintained for three years and made readily retrievable for all dangerous drugs administered in accordance with section 4729.45 of the Revised Code and rule 4729:1-3-03 of the Administrative Code and shall include the following information:

(1) Full name and address of the patient;

(2) Patient's date of birth or age;

(3) Patient's applicable allergy information;

(4) Date of administration;

(5) Name, strength, and dose of the drug administered;

(6) Lot number and expiration date of the drug;

(7) Route of administration;

(8) Location of the injection site;

(9) Documentation of test results required prior to the administration of an opioid antagonist in accordance with rule 4729:1-3-03 of the Administrative Code;

(10) Required physician notification pursuant to rule 4729:1-3-03 of the Administrative Code;

(11) Positive identification of the administering pharmacist; and

(12) Identification of the person who provides permission to administer the dangerous drug pursuant to rule 4729:1-3-03 of the Administrative Code.

(M) Dangerous drug administration records may be electronically created and maintained if done so in accordance with the standards set forth in paragraph (E) of this rule.

(N) A waiver of the requirement for electronic positive identification in paragraph (D) of this rule may be granted by the board upon written request of a pharmacy.

(1) The request shall include all information, as specified by the board, to determine if it is in the public interest to waive the electronic positive identification requirement. The board reserves the right to request additional information from the pharmacy and

conduct an inspection of the pharmacy pursuant to rule 4729:5-3-03 of the Administrative Code prior to rendering its decision.

(a) The pharmacy must demonstrate that the requirement of electronic positive identification would impose an undue economic hardship and that the proposed system of recording positive identification is sufficient to ensure safety to the public and to patients given the pharmacy's prescription volume and staffing.

(2) If the board approves a waiver, the pharmacy shall retain the waiver until there is a change of ownership or the pharmacy acquires a new computerized system to dispense dangerous drugs, unless otherwise determined by the board.

(3) A pharmacy that is denied a waiver by the board will be provided with a written explanation of the denial.

(4) In determining whether to grant the waiver, the board shall consider, at a minimum, all of the following:

(a) Whether the requirement to implement electronic positive identification will be cost prohibitive so as to impact the continued viability of the business;

(b) The average number of dangerous drugs dispensed at the pharmacy to determine the reliability of a non-electronic method of positive identification;

(c) The results of an inspection authorized in accordance with rule 4729:5-3-03 of the Administrative Code; and

(d) A review of past disciplinary actions taken against the pharmacy, or against an individual while employed by the licensee, that are based, in whole or in part, on drug security, record keeping violations, errors in dispensing, and/or any other disciplinary actions deemed relevant to the board's analysis.

(O) A pharmacy that utilizes a computerized system to dispense dangerous drugs may use hardcopy records and manual signatures to capture positive identification for any of the following:

(1) Compounding and the dispensation of compounded drugs; and

(2) Ancillary services as defined in rule 4729:5-5-02.1 of the Administrative Code.